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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 98N–0877]

Medical Devices; Performance Standards for Dental and Mammographic X–Ray Devices; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to exempt panoramic dental x-ray units from the requirement that they be manufactured with exposure timers which automatically reset to zero upon premature termination of an exposure. Removing the automatic timer reset requirement will not compromise the quality of the radiographic image and will protect patients from being subjected to unnecessary radiation due to repeat radiographs. FDA also proposes five changes to align the performance standard with the equipment requirements issued under the Mammography Quality Standards Act of 1992 (MQSA). First, the agency proposes to remove any reference to the use of equipment not specifically designed for mammography from the performance requirements for mammography equipment. Second, FDA proposes that the mammographic field alignment requirements restrict the irradiation beam to less than 2 percent of the source-image receptor distance (SID) beyond the image receptor edges. Third, it is proposed that the definition of an image receptor support device be amended to specify that it must provide a primary protective barrier for any orientation of the x-ray tube and image receptor support device assembly. Fourth, it is proposed that the useful beam must be confined to the dimensions of the

primary barrier provided by the image receptor support device (except on the chest wall side). Fifth, it is proposed that exposures not be permitted without the primary barrier in place.

DATES: Written comments by (*insert date 90 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–0865.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 (Pub. L. 101–629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the Public Health Service Act (PHS Act) to Chapter V of the Federal Food, Drug, and Cosmetic Act (the act). Under the act (21 U.S.C. 301 *et seq.*), FDA is proposing to amend the performance standard for diagnostic x-ray systems and their major components. Performance Standards for Ionizing Radiation Emitting Products are contained in part 1020 (21 CFR part 1020). This standard was initially published in the **Federal Register** of August 15, 1972 (37 FR 16461). Since that time there have been several amendments, both to stay current with technological developments and to clarify the interpretation of the provisions. Additionally, the President's Radiation Protection Guidance to Federal Agencies for Diagnostic X-Rays, published on February 1, 1978 (43 FR 4377), recommended that the fundamental objective in performing x-ray examinations should be to obtain optimum diagnostic information with minimum patient exposure.

The radiographic equipment standards of § 1020.31 apply to diagnostic x-ray systems, including those used for dental radiography and mammography. The most recent amendments to

the performance standard, published in the **Federal Register** of May 3, 1993 (58 FR 26386), and corrected May 28, 1993 (58 FR 31067), and May 19, 1994 (59 FR 26402), did not affect the timer requirements for dental systems or the x-ray beam limitation on mammography systems. Most recently, the passage of the MQSA (Pub. L. 102–539) and issuance of interim and final MQSA regulations have focussed attention on the mammography equipment requirements contained in part 1020. Although the MQSA is directed to facility requirements for maintaining mammography quality, both the interim and the final MQSA regulations contain certain requirements for mammographic x-ray equipment that is also subject to the performance standard for diagnostic x-ray systems (58 FR 67558, 58 FR 67565, and 62 FR 55976).

The safety and performance aspects of panoramic dental systems were discussed with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) in 1996. TEPRSSC is a statutory advisory committee (21 U.S.C. 360kk(f)(1)(A)) that FDA is required to consult prior to proposing any electronic product performance standards under the act. TEPRSSC recommended that the performance standard be amended to exempt panoramic systems from the timer reset requirement. The issues of collimation of the mammography x-ray field and primary barrier transmission were presented and discussed with TEPRSSC at the 1997 meeting. The recommendation was that FDA amend the performance standard for diagnostic x-ray systems to allow the dimensions of the x-ray beam to exceed the image receptor dimensions by up to 2 percent of the SID, and that the beam be fully intercepted by the image receptor support device, except on the chest wall side. TEPRSSC also recommended that the primary barrier transmission requirement be retained, that manufacturers discontinue the practice of designing general purpose x-ray systems so that they may be used to perform mammography, and that manufacturers not promote or encourage their use for mammography. FDA has reviewed the recommendations of TEPRSSC and agrees with their recommendations. Accordingly, FDA is proposing to amend the performance standard as indicated as follows.

Amendments to performance standards for electronic products ordinarily become effective 1 year after the date of publication of the final rule to allow sufficient time for manufacturers to implement changes in design or production practices (21 U.S.C. 360kk(c)). FDA believes it would have good cause for prescribing an earlier effective date for these proposed mammography amendments, as unneeded delay in their implementation could lead to difficulties for mammography facilities because of confusion about the requirements of different government standards when the MQSA final regulations become effective in April 1999. FDA also feels that an unneeded delay in the final dental x-ray amendments could lead to problems for dental facilities. Because this proposed amendment clarifies a provision of the Federal standards, FDA believes that it will prevent misunderstandings by State regulators. FDA welcomes comments on the timeframe for implementation of a final rule.

II. Dental X-Ray Devices

A. Panoramic Dental Radiography

FDA established the requirement that exposure timers be automatically reset upon premature termination of an exposure because the agency believed that the resulting radiograph would not provide adequate diagnostic information because of insufficient exposure of the film. Further, it was felt that the continuation of the exposure was not advisable because any patient movement occurring for any reason would make it impossible to obtain an adequate diagnostic image. The rationale was that discontinuing exposure would ensure that the patient did not receive exposure to x-rays that was unnecessary since it would not produce a clinically useful radiograph. The requirement that the timer automatically be reset results in a repeat exposure from the start in order to achieve adequate radiographic quality.

In 1974, FDA determined through correspondence with a manufacturer of panoramic dental units that the timer requirement of § 1020.31(a)(2)(i) should not apply to the manufacturer's units. The manufacturer's units performed a panoramic sweep in 9 to 12 seconds. However, if the system

were stopped, it could resume the panoramic examination starting from where it was interrupted, and viable image data would still be obtained without the need to restart the panoramic view. This resumption was because of the design of the system and the manner in which the image was acquired. As the tube head of a panoramic system moves, so does the film, resulting in only a small portion of the film being irradiated at a given interval of time. A lead shield protects the unexposed and previously exposed parts of the film. Therefore, stopping and restarting of the exposure did not result in a radiograph which was unusable.

FDA notified the manufacturer that the panoramic dental unit would not be considered noncompliant with the performance standard of § 1020.31(a)(2)(i) and FDA has followed this interpretation for other panoramic dental units that perform in a similar manner since then.

B. Interpretations of the Performance Standard

Although the agency has exercised its discretion in not enforcing the timer requirement against manufacturers of panoramic dental units, FDA believes it is necessary to expressly exempt such units from the timer reset requirement. Section 542 of the act (21 U.S.C. 360ss) provides that any State or local standard applicable to the same aspect of performance as the Federal performance standard must be identical to the Federal standard. State and local officials in jurisdictions that have adopted requirements identical to § 1020.31(a)(2)(i) may enforce that requirement against manufacturers of panoramic dental units. Thus, to ensure consistency among Federal, State, and local requirements, FDA believes a change to the performance standard is necessary.

III. Mammography X-Ray Devices

A. Equipment Requirements and the Mammography Quality Standards Act

The MQSA and FDA's regulations governing mammography establish quality standards for facilities performing mammography to assure safe, reliable, and accurate mammography nationwide. FDA would like to ensure that the standards pertaining to radiation emitting electronic products, including mammography equipment, and those pertaining to the facilities that use such

equipment are in accord. Presently, the equipment standard specifies that the x-ray field must be contained within the borders of the image receptor, except on the chest wall side (§ 1020.31(f)(3)). The equipment standard also indicates a limit on the maximum allowable transmission through the image receptor support device. FDA proposes to modify the field alignment requirements to allow the x-ray field to extend beyond any edge of the image receptor in such a manner that this extension does not exceed 2 percent of the SID. The limit on x-ray transmission through the image receptor support would still apply except on the chest wall edge.

The MQSA requires that only equipment specifically designed for mammography can be used by facilities. Systems designed for other types of studies but provided with special attachments for mammography are no longer allowed under MQSA. As a result, it is proposed that § 1020.31(f)(3) be changed to be consistent with the MQSA requirements by deleting the language which previously included general purpose radiographic systems.

B. Field Size Limitations

Section 1020.31(f)(3) pertains to field limitation of mammographic x-ray equipment. It states that:

[R]adiographic systems designed only for mammography and general purpose radiographic systems, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.

The previous requirement holds the manufacturer or assembler of the equipment (not the facility) responsible for providing means to limit the x-ray field at the image receptor plane so that the x-ray field does not extend beyond any edge of the image receptor except the side adjacent to the chest wall. FDA's standard also defines the image receptor as a fluorescent screen, radiographic film, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into

a visible image or into another form which can be made into a visible image by further transformations.

The image receptor is the film itself (where film is used). In this case, neither the image receptor assembly nor the cassette holder is considered the image receptor. For fixed aperture devices, in order to assure that the x-ray field does not exceed the edges of the image receptor, the manufacturer must restrict the beam so that unexposed edges will appear on the developed film to account for film size tolerances or shifts inside the cassette. For stepless adjustable beam-limiting devices (BLD), the means provided by the manufacturer to assure compliance with the previous requirement is that the x-ray field must always be slightly smaller than the light field. Thus, when the operator adjusts the light field to the image receptor size, the x-ray field will indeed be contained within the borders of the image receptor (except of course on the side adjacent to the chest wall which is allowed a tolerance of up to 2 percent of the SID). For this type of BLD, the operator may also open the field to any size and is limited only by the maximum opening allowed by the system which should be restricted by the limits established by § 1020.31(m).

One aspect of the MQSA requirements addresses the proper viewing of mammography films. The standard practice is that these be read on view boxes (light boxes) with the ambient room light levels reduced. Unexposed film areas and parts of the light box should be masked to prevent the bright light surrounding the radiograph from interfering with the interpretation under these conditions. It is possible to tailor the masking of these areas for individual cases; however, this becomes a problem when large numbers of films are viewed, as in a breast screening program. The work of the radiologist is expedited if radiographs are produced without transparent margins. Another consideration is that the clinical image review process of accreditation bodies, such as the American College of Radiology, is simplified by having to create only one mask size, rather than having to create individualized masks for each facility. A practice used by some facilities with variable aperture BLD is to increase the x-ray field size to expose the borders of the film and thus reduce the need to provide a different mask for each film. However, fixed aperture systems

cannot open up or adjust the field size to cover the entire film to eliminate the unexposed borders. The radiation safety concept of collimating the x-ray beam to the body region of interest is valid in mammography, but it is of little relevance since the breast is normally completely irradiated. There is little evidence that changing the x-ray field coverage from just inside the edges of the film to just outside the edges of the film would make a clinically significant difference in image quality or significantly raise the radiation safety risk to either the patient or the equipment operator.

Adoption of the 2 percent tolerance would bring FDA into harmonization with the International Electrotechnical Commission (IEC) equipment standard. The IEC has developed a draft standard which addresses the requirements for the safety of mammographic x-ray equipment and mammographic stereotactic devices (IEC 62B/60601-2-45). Included in this document is a requirement that the x-ray field not exceed the dimensions of the image receptor by more than 2 percent of the source-image receptor distance, in agreement with what FDA is herein proposing. In the rationale given for this decision, the IEC included a discussion of currently accepted clinical practice that involves irradiating the same field size area for all patients, which in most cases substantially overlaps the actual region of interest. The increasing use of brighter view boxes and radiographs of higher optical densities is also mentioned, along with the importance of eliminating view box glare at the film edges. Balancing this against the basic radiation safety guidance of irradiating only the area of interest, the IEC concluded that, in this case, any potential increase in patient dose was justified by the overall benefit to the population being screened.

With variable aperture collimation there is no control over how much the x-ray beam can exceed the image receptor since the operator can adjust the field larger. However, the field should not be larger than the image receptor supporting device to prevent primary beam irradiation of other parts of the body.

Manufacturers of mammographic equipment have requested that FDA address the confusion between the requirements of the x-ray performance standards and the MQSA. FDA is not requiring that the x-ray field must exceed the area of the x-ray film. Rather, FDA is providing flexibility

by allowing the manufacturers to design their equipment so that the x-ray field may be used to darken the film to its borders if desired by the purchaser. Whether the film has borders or is darkened to the edges, proper masking of the film for viewing is still needed for best viewing results.

C. X-ray Transmission Through Primary Barrier

In addition to the requirements for x-ray field limitation and alignment for mammography, requirements for primary beam transmission became effective on September 5, 1978. The current requirement, § 1020.31(m), states that:

[F]or x-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 2.58×10^{-8} C/kg (0.1 mR) for each activation of the tube.

The intent of this requirement is to provide radiation safety for the patient beyond the plane of the image receptor. Based on the restrictions described in § 1020.31(m) and the accompanying preamble, it is clear that the intent of the image receptor supporting device (IRSD) requirement was to reduce irradiation beyond the plane of the image receptor or the IRSD which could strike the patient. Thus, primary irradiation must be blocked and reduced for any accessible area 5 centimeters (cm) beyond the image plane. It is understood that for the chest wall side some primary beam irradiation would not be blocked by the IRSD and this is allowed in order to obtain as much diagnostic information from the chest wall side of the breast as possible. Since all of the primary beam (except on the chest wall side) should be intercepted by the IRSD, a measurement only need be made of the transmitted beam and at the shortest SID which would yield the largest transmission reading. While it may be safe to allow the x-ray field to exceed the image receptor by a certain amount, and necessary in order to adequately image the breast tissue anatomy in the chest wall area, there is no adequate justification for allowing the primary beam to extend beyond the primary barrier provided by the IRSD except at the chest wall side.

An additional problem arises for those manufacturers who use their cassette as the image receptor support device and have placed attenuating material on the bottom of the cassette in order to meet the transmission requirements. Should the edge alignment requirements be increased by amendment, these manufacturers would need to add an additional barrier to their system or continue to restrict the beam to prevent unattenuated primary beam beyond the plane of the IRSD. FDA feels that the definition of an image receptor support which appears in § 1020.30(b) should be changed to indicate that the support device must provide a primary protective barrier. This should apply for any orientation of the x-ray tube and image receptor support device assembly, not just in the horizontal plane as it currently states. Furthermore, exposures should not be possible without the image receptor support device, acting as the primary barrier, being in place.

The primary barrier transmission requirement is an absolute restriction. The limit specified leaves the manufacturer free to choose the method to reduce the x-ray transmission so that it does not exceed 2.58 $x10^{-8}$ coulombs (C) per kilogram (kg) (0.1 milliroentgen (mR)) per exposure. The image receptor support device must intercept all of the primary beam (except the chest wall side) and reduce the transmitted radiation to what is considered safe and feasible. Any changes in the field sizing should ensure adherence to the transmission requirements. In the past, all systems in use for mammography had fixed aperture plates for x-ray field determination. The advent of the variable aperture BLD for mammography is potentially a problem if a beam-limiting device is opened so that primary x-rays extend beyond the primary barrier provided by the image receptor support device. In order to prevent this, a variable aperture BLD must provide some restriction on the maximum field size to ensure that the primary beam is contained within the IRSD which is also a primary barrier. In other words, with the collimator opened as wide as possible, primary x-radiation should not extend beyond the barrier, at any available SID, except at the chest wall side, and the exposure level 5 cm beyond this barrier should be less than the exposure value given previously.

FDA's position on primary barrier transmission is in agreement with that taken by the IEC. Their draft standard on safety requirements for mammography systems (62B/60601-2-45) requires primary barrier shielding to extend at least to the projection of the patient support at the chest wall side, and to extend at least 1 percent of the SID beyond the x-ray field at the other sides.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(a) and (i) and 25.34(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the* **Federal Register**), submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VI. Analysis of Impacts

FDA has examined the impact of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive

Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and therefore is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. An analysis of available information suggests that costs to the entities most affected by this rule, including small entities, are not expected to be significant, as described in the following analysis. FDA believes that the proposed regulation will not have a significant impact on a substantial number of small entities, but conducted an initial regulatory flexibility analysis to ensure that impacts on small entities were assessed and to alert any potentially impacted entities to the opportunity to submit comments to the agency. This proposed rule will not impose costs of $100 million or more in either the private sector or State, local, and tribal governments in the aggregate. Consequently, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

In part, the proposed rule codifies the equipment performance standards established under the Mammography Quality Standards Act of 1992 (MQSA) (Pub. L. 102–539) by proposing to require only x-ray systems designed solely for mammography be marketed for mammography. This proposal updates the x-ray performance standard to reflect a standard already enforced under MQSA. Consequently, FDA expects no economic impact from this portion of the proposed rule.

The proposed rule also proposes to permit the x-ray irradiation field to extend to the edges of the x-ray film but not beyond the primary barrier provided by the image receptor support device. It further proposes to change the definition of an image receptor support device, clarifying that it must provide a primary protective barrier and that exposures should not be possible without the image receptor support device being in place, acting as the primary barrier. Exposing all of the film allows one size of film mask to be used for proper viewing of mammography films using light boxes while not allowing the beam beyond the primary barrier protects the patient from unnecessary exposure to radiation. FDA believes that most of the image receptor support devices that are currently in use provide a primary protective barrier that meets the requirements in the

proposed amendments to §§ 1020.30(b) and 1020.31(m). In addition, when the manufacturer's design of the cassette holder provides the primary barrier attenuation itself, then the cassette holder is considered a part of the image receptor support device. Therefore, FDA estimates that the proposed amendments to §§ 1020.30(b) and 1020.31(m) will impose minimal new costs. This proposal also allows more flexibility for mammography facilities and accreditation bodies without compromising the public health and may reduce costs to mammography facilities and accreditation bodies by simplifying the masking of images.

The proposed rule further proposes to exempt panoramic x-ray dental units from the requirement that they be manufactured with exposure timers which automatically reset to zero or the initial setting upon premature termination of an exposure. For panoramic dental exposures, interrupting the exposure does not affect the quality of images already taken. Consequently, restarting the exposure at the initial starting point exposes patients to unnecessary radiation. This proposal removes a regulatory requirement, while still protecting the public health, and may reduce costs to dental facilities and patients.

The Safe Medical Devices Act of 1990 (Pub. L. 101–629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the PHS Act (42 U.S.C. 201 *et seq.*) (PHS Act) to chapter V of the act. These provisions regulate electronic products which emit radiation. On October 27, 1992, the MQSA (Pub. L. 102–539) was enacted to establish uniform, national quality standards for mammography. MQSA (42 U.S.C. 263b(f)(1)(B)) requires the use of radiological equipment specifically designed for mammography to be used for mammography. Similarly, § 900.12(b)(1) of the interim and final mammography regulations prohibits the use of conventional radiographic equipment for mammography. FDA has reviewed related Federal rules and has not identified any other rules that duplicate, overlap, or conflict with the proposed rule. FDA has also identified no new reporting, recordkeeping or other compliance requirements associated with this proposed rule.

There are approximately 10,000 mammography facilities in the United States. Because this potential change in the performance standard only applies to machines manufactured after the effective date of the final rule, the associated cost does not apply to those machines manufactured prior to that date. FDA estimates that approximately 10 percent of facilities replace their mammography machines in any 1 year. At this time, FDA is unable to estimate the demand for the proposed systems modifications. As discussed previously, the proposed change concerning x-ray beam collimation is less restrictive than the present standard. FDA estimates the cost per system to be between $0 and $5,000 if the system modification is made during production.

There are approximately 138,500 dental facilities in the United States of which 40 percent provide access to panoramic dental x-ray units. An uncertain number of these facilities may request the manufacturer to remove the automatic reset of the exposure timer on their panoramic machines; however, they are not required to do so. FDA believes that the facility will only make this change if it is economically or clinically advantageous to do so. FDA estimates it will cost a facility an amount equal to what would be assessed for a routine service call (approximately $150.00 or less) to remove the automatic reset function for premature termination of an exposure for existing systems. FDA believes that manufacturers no longer manufacture panoramic dental x-ray units with automatic reset exposure times.

Most, if not all, of the mammography facilities and dental facilities would be considered small under the criteria established by the Small Business Administration. FDA's registration system shows five manufacturers of panoramic dental units. Of the domestic manufacturers, none would be considered small entities. There are approximately 10 manufacturers of mammography x-ray systems. Of these manufacturers, none would be considered small entities. FDA invites comments on this analysis of the number of entities that may be affected by the proposed changes to the performance standard.

For the mandatory changes proposed for image receptor support devices, FDA believes that most of the image receptor support devices that are currently in use provide a primary barrier

that is capable of meeting the requirements in the proposed amendments to §§ 1020.30(b) and 1020.31(m). There are approximately 10,000 mammography facilities in the United States. Because this potential change in the performance standard only applies to systems manufactured after the effective date of a final rule, the costs associated with any changes that may need to be made, would not apply to those machines manufactured prior to that date. FDA estimates that approximately 10 percent of facilities replace their mammography systems in any 1 year (10 percent of 10,000 = 1,000). FDA estimates the cost per system to be between $0 and $2,000 in the event that any manufacturers are required to implement design or production changes to ensure that exposures not be permitted on their systems without a primary barrier being in place. FDA estimates approximately 95 percent of the systems currently being marketed already meet this requirement. With an annual mammography system replacement rate of 10 percent (i.e., 1,000 new systems purchased per year), FDA estimates only approximately 5 percent of these 1,000 systems may increase in cost to meet the requirement. To calculate the annual cost, FDA estimates a cost of $0 to $2,000 per system multiplied by 50 systems (5 percent of 1,000 = 50). Using this estimate, the costs are expected to be approximately, $0 to $100,000.

Under these proposed changes to the performance standard, FDA allows manufacturers and facilities to decide whether to implement any device modifications in response to the greater flexibility proposed in these mammography collimation requirements. If the benefits associated with the flexibility proposed in this rulemaking are outweighed by the costs to the facility, the facility can choose to not purchase a device which has been modified in response to the greater flexibility proposed in this rulemaking. With regard to the mandatory change proposed for the primary barrier requirement, FDA believes that the great majority of the image receptor support devices that are currently being manufactured provide a primary barrier that is capable of meeting the requirements in the proposed amendment to § 1020.31(m). Therefore, FDA does not anticipate that the proposed amendment to § 1020.31(m) will impose any significant costs.

Because most of these proposed changes to the mammography performance standard and the proposed change to the timer requirement for panoramic dental systems provide for greater flexibility, FDA considered no alternatives to accomplish the stated objectives of the applicable statutes. For the primary barrier standard proposed in § 1020.31(m), FDA considered not requiring the primary barrier to be in place to intercept the useful beam. This alternative was rejected because without the primary barrier in place, patients would be exposed to unnecessary radiation.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1020 be amended as follows:

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

1. The authority citation for 21 CFR part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360gg–360ss, 371, 381.

2. Section 1020.30 is amended by alphabetically adding a definition to paragraph (b) to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(b) * * *

Image receptor supporting device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

* * * * *

3. Section 1020.31 is amended by revising paragraphs (a)(2)(i), (f)(3), and (m) to read as follows:

§ 1020.31 Radiographic equipment.

* * * * *

(a)

(2) * * *

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

* * * * *

(f) * * *

(3) *Systems designed for mammography.* (i) Mammographic beam-limiting devices manufactured after (the effective date of the final rule) shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system which performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems which allow changes in the SID, the SID indication specified in paragraphs

(f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Each image receptor supporting device intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

* * * * *

(m) *Primary protective barrier for mammography x-ray systems.* For mammography x-ray systems manufactured after (the effective date of the final rule).

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier which intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed 2.58×10^{-8} C/kg (0.1 mR) for each activation of the tube.

(4) Compliance shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and

by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

Dated: October 21, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

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